

ProSafe

*Promoting the Implementation
of Safe by Design*

Special ProSafe Newsletter:

Launch and promotion of the ProSafe Joint Transnational Call

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I) Editorial

The H2020 project ProSafe was launched a year ago. Looking back at this past year, I am happy to conclude that we are making good progress in achieving our goals. The “White Paper process” is on track. This process includes the evaluation of results of a broad variety of nanosafety projects among which EC funded projects such as NANoREG, MARINA, OECD projects and other projects. Focus will be on the evaluation of methods and data sets for testing and assessing risks of nanomaterials in a regulatory context. For this evaluation, a ProSafe Task Force chaired by Klaus Steinhäuser (DE) and Phil Sayre (US), has been established. The members of this Task Force are senior experts covering a wide range of expertise in the field of nanosafety. Recently the Task Force successfully performed a pilot test for this evaluation. The results of the evaluation will be laid down in what is called the Joint Document. A draft of this document will be discussed during a Scientific Conference that will be organized by OECD and ProSafe at Paris, November 29 - December 1, 2106.

The Joint Document will be an important element of the White Paper; a document that provides building blocks for regulators and industry to address Environmental Health and Safety (EHS) aspects of Manufactured Nano Materials (MNM) including Safe by Design (SbD). ProSafe activities like a Foresight Study and the definition of standard approaches for (EHS) data management are also now generating input for the White Paper.

Another pillar of ProSafe is facilitating the incorporation of SbD in the core of innovation, research and development of companies active in the field of nanotechnology. Especially for Small and Medium Enterprises a successful implementation of this concept will be a prerequisite to fully exploit the potential of nanotechnology.

To support the implementation of the SbD concept, the Joint Transnational Call recently has been launched. In this Call several national funding agencies cooperate in the development of a customized implementation and verification of the SbD concept in R&D - and innovation - projects of industrial companies. Additionally, the Twinning of projects will foster the integration of the NANoREG SbD concept in industrial innovation processes.

This dedicated ProSafe Newsletter informs interested parties on content and procedures regarding the Joint Transnational Call and the Twinning of projects.

I hope that this Newsletter inspires interested parties to submit a proposal for this Call and to use the offer of ProSafe for the Twinning of projects.

*Tom van Teunenbroek
Coordinator ProSafe
Ministry of Infrastructure and the Environment, The Netherlands*

II) The ProSafe Joint Transnational Call supporting Safe-by-Design approaches

The NANoREG Safe-by-Design Concept with regulatory preparedness

(Karl Hoehener, TEMAS AG, Switzerland)

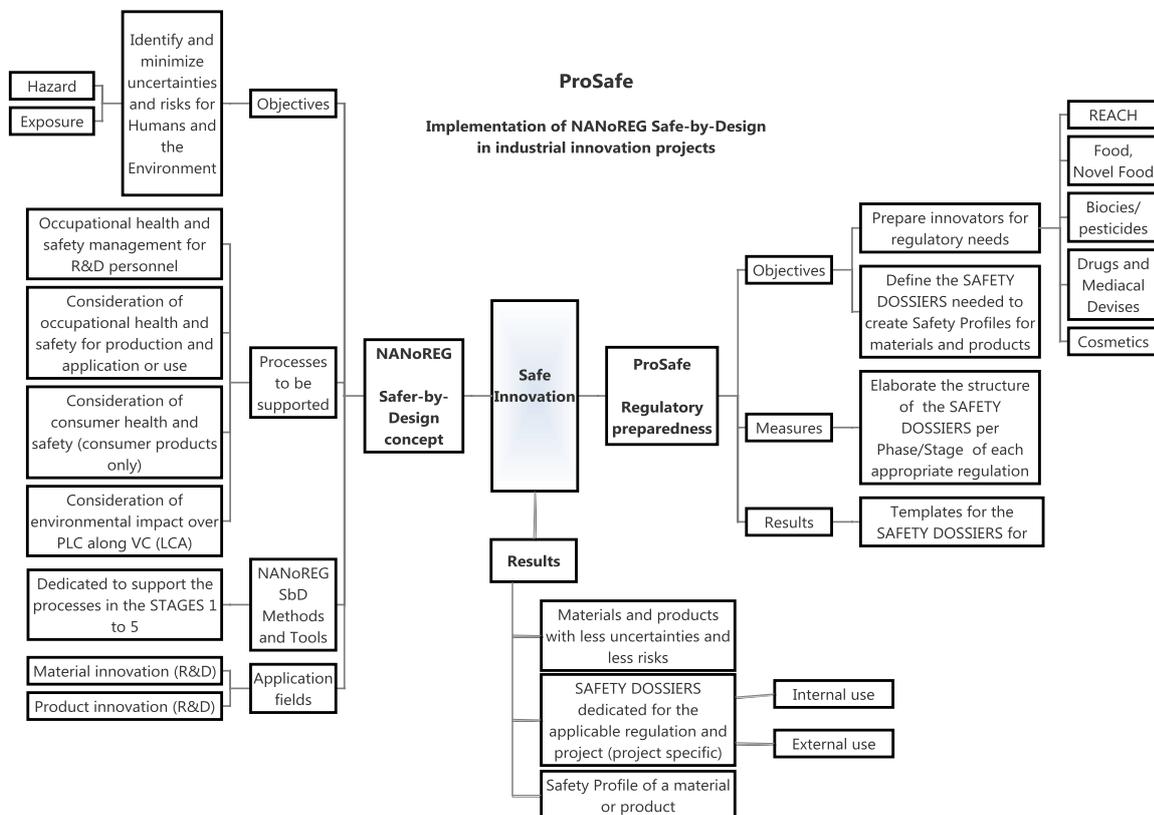
Safe Innovation is seen as an important tool to boost economic growth, sustainable development, and as one of the most important drivers of societal prosperity. Likewise, material and product innovations are among the most important drivers of an industrial enterprise's prosperity.

Therefore, emerging technologies such as nanotechnology and new materials can rely on huge public and private funding to stimulate their development into commercial utilization.

However, if and when innovative nano products get near to commercialization, discussions about human and environmental safety (EHS) seem to threaten the investments because industry and regulatory authorities have a different opinion and the regulation takes place with a significant time lag. To improve the present situation, it is inevitable that there must be a closer collaboration and a framework between industry and regulatory authorities.

Such a framework would be the safe innovation approach as a combination of the NANoREG Safe-by-Design (SbD) concept with regulatory preparedness. Through this combination, safe innovation can become a common activity of industry and regulatory authorities.

The concept of Safe-by-Design is not new, as similar concepts for other purposes such as Quality by Design have been used for years by industry.



Overview of Safe Innovation

There is no generally accepted definition of Safe-by-Design. The understanding is diffuse and sometimes misleading.

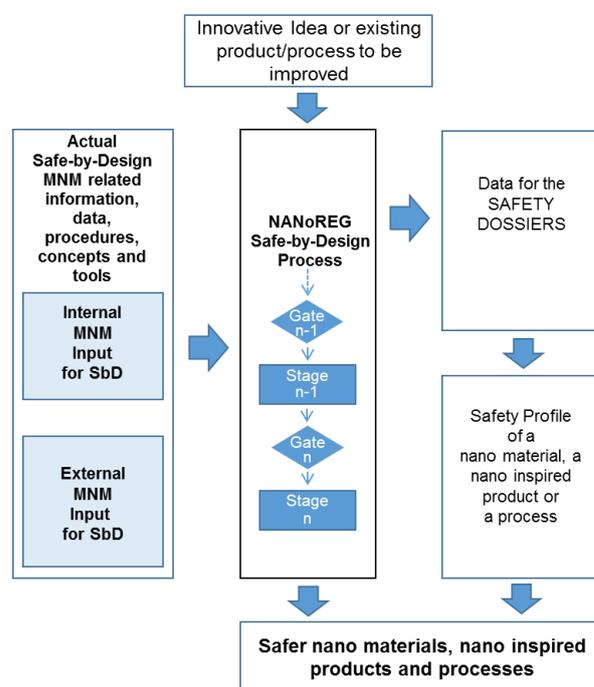
The overall objectives of the NANoREG Safe-by-Design concept are:

- Only safe nanomaterials and nano-inspired products will enter the market!
- Transparency on information along the innovation process
- Timely identification and reduction of uncertainties
- Identification and management of risks
- Be prepared for actual and future regulations

The NANoREG Safe-by-design concept consists of three main elements:

- The solid SbD-process stays a central element of the SbD-concept. It is divided into concerted phases/stages, which are interconnected via the milestones/gates. These have the function to trigger the next phase/stage. The respective criteria will be defined during the start of the project. A project with phases/stages can cover the entire value chain of a material or product, or a section of it (Figure 5). The integration of the SbD concept in the innovation or R&D processes of a company will be structured via these phases/stages and the respective milestones/gates.
- The backbone of the SbD-concept is the available scientific knowledge and the facts as well as robust data on the safety of nanomaterials and products containing nanomaterials. From this backbone, the necessary procedures, instruments and tools for the SbD process will be selected and harmonized.

- In the Safety Dossiers, the safety-relevant data and information will be collected during the R&D or innovation process. It will be the basis for the elaboration of the Safety Profile of the relevant material or product. At the beginning of a project, the structure of the contents of the safety dossier will be established and matched with the applicable regulation.



The NANoREG Safe-by-Design concept

The NANoREG SbD concept is intended and designed as an extension of current industrial innovation processes, see figure page 7 . It can be used by any industrial enterprise along nano-materials' or nano-products' value chains. For the smooth integration in existing industrial innovation processes, the NANoREG Safe-by-Design concept has a modular structure.

A detailed description of the NANoREG Safe-by-Design concept is available on the [ProSafe Website](#).

The ProSafe Joint Transnational Call supporting Safe-by-Design approaches

(Rita Cavaleiro, FCT - Fundação para a Ciência e a Tecnologia, Portugal)

The ProSafe consortium launched the 2016 Joint Transnational Call to support the implementation of the NANoREG Safe-by-Design (SbD) concept in industrial innovation processes. The call was launched on 29th February 2016 and its **closing date for submission of proposals is 20th May 2016 (12:00 CET)**.

The NANoREG Safe-by-Design (SbD) concept is intended and designed as an extension of current industrial innovation processes. This SbD concept focusses on the timely identification and management of uncertainties and potential risks during an innovation project. The NANoREG SbD concept could be used by any industrial enterprise along nano-materials' or nano-products' value chains.

Aim of the Call:

The aim of the ProSafe Joint Transnational Call is to develop, focused on the needs of industrial companies, a customized implementation and verification of the SbD concept for R&D- and innovation-projects. Above that, the call will help to find and implement SbD working concepts generally applicable for specific industrial branches.

Topics of the Joint Transnational Call:

Topic 1 – Integration of the NANoREG Safe-by-Design (SbD) concept in industrial innovation processes along the entire, or a part of, the value chain of a manufactured nano material or a nano-inspired product.

Topic 2 – Gaining and collection of knowledge for the sustainable implementation of the NANoREG Safe-by-Design (SbD) concepts in industrial innovation processes.

Topic 3 – Social Science research in support of awareness and impact of the NANoREG Safe-by-Design (SbD) concept on nanotechnology innovations for the society.

Topic 4 – Development of methods and knowledge for a downstream approach as complement for existing products using the NANoREG Safe-by-Design (SbD) Concept.

Participating funding organizations:

Austria – Austrian Research Promotion Agency (FFG) / Federal Ministry for Transport, Innovation and Technology (BMVIT)

Portugal – Foundation for Science and Technology (FCT)

Romania – Executive Agency for Higher Education, Research, Development and Innovation Funding (UEFISCDI)

Switzerland – Commission of Technology and Innovation (CTI)

How to submit the proposals:

The proposals should be submitted by the project's coordinator via the ProSafe Electronic Proposal Submission System.

More information:

For more information and to download the call documents, please consult the call webpage on <http://www.h2020-prosafe.eu/prosafe/?p=644>.

Call Secretariat:

Rita Cavaleiro / Marta Norton

Foundation for Science and Technology (FCT), Portugal

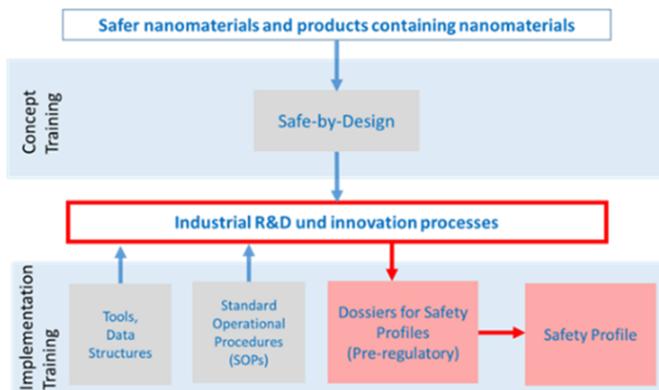
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Safe-by-Design Training

(Jürgen Höck, Karl Höhener, TEMAS AG, Switzerland)

Training and education of all involved personnel with an appropriate knowledge about Safe-by-Design (SbD) is paramount to its successful implementation in industry. Even today, a proper innovation process execution and risk analysis/management is often hampered by a lack of training.

The main driver for the trainings on Safe-by-Design is the development of “Safe nanomaterials and products containing nanomaterials”.



Overview of the main driver, industrial R&D and innovation process and the two Safe-by-Design Trainings

The SbD training is divided into two modules:

- Concept Training on Safe-by-Design as general information for interested persons
- Implementation Training of Safe-by-Design in industrial innovation processes

Concept training

The target groups of the Concept Training are companies and researchers interested to elaborate a proposal for the ProSafe Joint Transnational Call 2016 or to study the opportunity to participate in ProSafe’s offer for

the Twinning of projects supporting Safe-by-Design.

The Concept Training provides an overview over NANOREG Safe-by-Design concept. This overview is, along with some basic information, a prerequisite for a successful SbD implementation.

The backbone of the NANOREG Safe-by-Design concept is a structured innovation model. This will be addressed as a need for a successful industrial implementation.

An overview of the different SbD sub-processes, the data management as well as the content of the Safety Dossiers for the different regulations and Safety Profiles are part of the training.

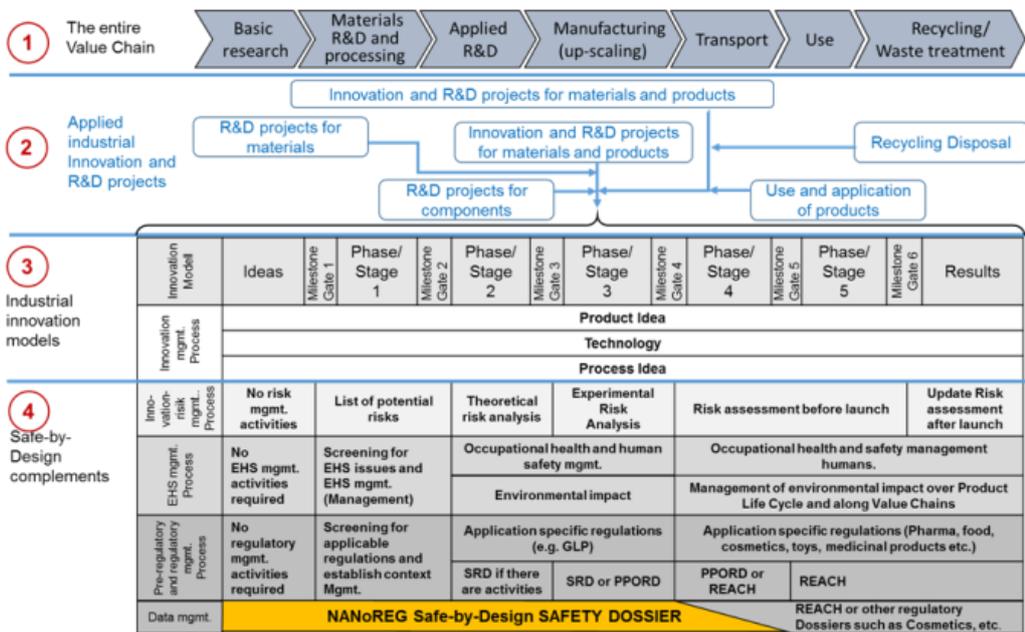
The training is organized as a half-day event. For more information about this training opportunity, please contact karl.hoehener@temas.ch.

Implementation Training

Due to confidentiality requirements of such a training, there will be no public training available. The Implementation training is individually tailored for each project in accordance with its specific requirements and adapted to the existing industrial innovation model.

The NANOREG Safe-by-Design (SbD) concept can smoothly be integrated in industrial innovation projects and in existing innovation models or R&D processes. For this, no fundamental adjustments to the models are necessary; independent of which parts of the value chain will be addressed by an R&D or innovation project. The SAFETY DOSSIER creates transparency, pointing to uncertainties and is the basis for the Safety Profile of a material or product.

An overview of the integration of NANOREG Safe-by-design in industrial innovation processes is illustrated in the figure below, containing four elements.



Based on the data of the SAFETY DOSSIER, the safety profile of a material or product will be elaborated.

The target groups of the Implementation Training are the members of a dedicated project implementing NANoREG Safe-by-Design.

Integration of Safe-by-Design in industrial innovation and R&D projects along the value chain

The Implementation Training addresses the following topics:

- 1 Exemplary illustration of a value chain as a basis for the arrangement of the various innovation and R & D projects along this chain.
 - 2 Illustration of the arrangement of different types of Innovation- and R&D projects along the entire value chains of a material or product.
 - 3 Exemplary illustration of an industrial innovation model with the different phases / stages and the corresponding milestones/gates in between.
 - 4 Representation of the various sub-processes within the NANoREG Safe-by-Design concept such as: Innovation risk management process, EHS management process, pre-regulatory and regulatory management process.
- a) Implementation of the NANoREG Safe-by-Design concept into the existing innovation model;
 - b) Definition of the contents of the different Phases/Stages and the nano-specific milestone/gate-specifications;
 - c) Definition of the Safe-by-Design sub-processes;
 - d) Selection of the nano-specific instruments for the different phases/stages;
 - e) Creation of the Safety Dossier for the Safety Profiles;
 - f) Realization of the innovation project according to the usual processes in the company;
 - g) Creation of the Safety Profile.

The data from the various Safe-by-Design sub-processes are collected and grouped in NANoREG Safe-by-Design SAFETY DOSSIER and the dossier for the related regulation.

IV) Twinning of projects supporting Safe-by-Design approaches

(Karl Hoehener, TEMAS AG, Switzerland)

Nanomaterials are an important success factor for innovations with competitive properties of products at market costs. For the safety of a product or a material of the producer/distributor is responsible. This is as special challenge to companies, because corresponding regulations are - in many cases - published years after the innovation has entered the market. Therefore, precautionary principles such as safe-by-design are of great benefit for businesses as well as government funding agencies of such innovation projects.

Twinning of projects is the result of the integration of the NANoREG Safe-by-Design concept in industrial innovation processes. The challenging vision of “Twinning” is that only safe nanomaterials or products with nanomaterials will enter the market!

The implementation of this vision is a major challenge for the stakeholder groups:

- ✓ Public innovation and R&D funding agencies responsible for support and funding of projects developing or using nano scale materials, and
- ✓ Industrial innovators making use of the opportunities nanomaterials are offering.

For Governmental R&D and Innovation Funding organizations, ProSafe is offering a collaboration in order to achieve benefits from the integration of SbD in current and future national projects and calls, addressing nanomaterials and products containing nanomaterials. The aim of this collaboration is the development of safe nanomaterials and nano-inspired products, according to the current state of knowledge and regulations. For more information consult the [ProSafe Website](#).

V) Industry engagement

(Iolanda Olivato, ECAMRICERT, Italy)

Joint Transnational Calls and Twinning of Projects are dedicated to industries. There is the need to improve the existing networks, starting from what was already established within SIINN and NANoREG projects.

Within ProSafe, liaisons with industry are based on three possible levels of cooperation:

1. as interested industry or industry association: this is for industries that want to be informed about SbD development and implementation. No formal requirements from your side!
2. as strategic partner for policy and regulatory issues: you will become part of a group that will advise ProSafe. This level is for industries that want to have a say in the SbD development and regulatory acceptance. You could become a member of the Strategic Policy Development Group, or be considered privileged partners;
3. as partners in SbD and innovation-related projects: ProSafe has developed Joint Transnational Calls as one of the instruments for addressing the SbD integration along the entire or a part of the value chain of a nanomaterial or a nano-inspired product. ProSafe encourages the development of proposals addressing the calls involving industry and research centers.

Industry that are willing to cooperate with ProSafe in any capacity can refer to a specific website section aiming to disseminate the SbD information and the ProSafe aims to industry, as well as to build an industry inventory. Through a link it is possible to register and engage in the ProSafe network, by providing few data.

The registration form is at the following link: <http://www.h2020-prosafe.eu/prosafe/?cat=32>